

EU Declaration of Conformity

MANUFACTURER:	APOLLO HEALTHCARE TECHNOLOGIES LTD		
MFG. ADDRESS	Unit A1 Gildersome Spur, Morley, Leeds, West Yorkshire, LS27 7JZ, United Kingdom		
PRODUCT NAME:	Morpheus Air (Zero)	PRODUCT CODE:	APH166 (APH166Z)

	Class	MDD Classification Rule	Conformity Assessment	NBOG Code ¹	GMDN Code ²
CLASSIFICATION:	Ila	Annex-IX, Rule 9	Annex V	MD1108	47478

¹ Reference NBOG BPG 2009-3;

² Reference Global Medical Device Nomenclature™ (GMDN).

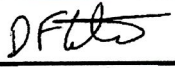

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE PRODUCT IS IN CONFORMITY WITH THE BELOW APPLIED STANDARDS.

STANDARDS APPLIED	DESCRIPTION
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021 IEC 60601-1-2:2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN IEC 60601-1-11:2015+A1:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62304:2009/A1:2015	Medical device software - Software life cycle processes
EN IEC 62366-1:2015 + AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 7010:2011 (Second Edition)	Graphical symbols - Safety colours and safety signs - Registered safety signs
BS 7068:1989	Specification for alternating pressure air mattresses
EN ISO 15223-1: 2016 (Third edition)	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009/R2014	Biological evaluation of medical devices - Part 6: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

NOTIFIED BODY:	TÜV Rheinland LGA Product GmbH Tillystraße 2, 90431 Nürnberg, DEUTSCHLAND	IDENTIFICATION NUMBER:	0197
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EC	REP	PaMed Consulting Karol Pawelec, ul. Jeleniowska 202A/54, 25-564 Kielce, Poland Tel/Fax: +48 507 833 787 Email: ar@pamed-consulting.eu
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EC CERTIFICATE #:	DD 2285935-1											
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PLACE OF ISSUE	Unit A1 Gildersome Spur, Morley, Leeds, West Yorkshire, LS27 7JZ, United Kingdom	DATE OF ISSUE	06 July 2023									

SIGNATURES		
PRINT NAME	POSITION	SIGNATURE
DAVID FLETCHER	MANAGEMENT REPRESENTATIVE	
DAVID LOCKE	CHIEF OPERATING OFFICER	

END OF DOCUMENT